

REMARKS

Applicants wish to thank the Examiner for the courtesy extended in a telephone interview on December 16, 2002, which materially advanced prosecution of the case.

The Examiner remarked in the interview Summary Record that: "Applicant proposed to clarify 'separate and discrete' regions whereas WO 99/59427 keeps separation on microscopic level."

It will be clear from the above amendment and these remarks that the macroscopic separation of an oral comfort region and salivation region as separate and distinct regions distinguishes the claimed invention from WO 99/59427, or any combination of that reference with U.S. Pat. No. 6,231,900 (Hanke).

The Examiner also remarked that the interview touched on functional characteristics of the claimed product configuration ("Functional limitations: discussed irritant effect causes mechanical action.") Applicants have added Claim 24, to more clearly recite what was discussed in the interview and is described in the specification: that concentrated pockets of salivation agent cause movement of the piece in the mouth. Applicants also wish to make clear that Federal Circuit caselaw requires that functional limitations be considered. See, e.g., *In re Swinehart*, 439 F.2d 210 (CCPA 1971); *In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997) ("A patent applicant is free to recite features of an apparatus either structurally or functionally); *In re Venezia*, 530 F.2d 956 (CCPA 1976); *Plastic Container Corp. v. Continental Plastics of Oklahoma, Inc.*, 607 F.2d 885 (10th Cir.

1979), *cert. denied*, 444 U.S. 1018 (1980), on remand, 515 F. Supp 834 (W.D. Okla. 1980), *aff'd in part, reversed in part*, 708 F.2d 1554 (10th Cir. 1983) ("the idea that functional language *ipso facto* cannot precisely define novelty in structure was laid to rest in *In re Swinehart*. ...").

Claims 1-24 are now presented for examination. Claim 1 has been amended to more clearly recite that the salivation agent is concentrated in one or more discrete and separate region(s) of the confectionery product such that salivation is enhanced. New independent claim 23 is similar to claim 1, and incorporates the product limitations of dependent claims 6 and 9, reciting the preferred ingredients for each of the salivation and oral comfort regions. New dependent claim 22 limits the product essentially to one salivation region and one oral comfort region, which is the extreme case of separate and distinct regions. Claim 24, recites the above-mentioned limitation relating to increased movement of the piece in the oral cavity.

Support for the amendment to claim 1 is found at least at page 15, lines 5-16, and page 16, lines 1-15. Support for the new dependent claim 22 is found, for example, at page 18, lines 23 to 32 and the Examples. The limitations of claim 23 are found in claims 6 and 9 as originally filed. Support for the limitation of claim 24 is found, for example, at page 16, lines 9-10. No new matter has been added.

Regarding the alleged new issues identified in the Advisory Action as requiring further search and consideration, "one or more" regions is identical in scope with "a" region, because "a" region does not preclude the presence of more regions. Likewise, a

two-region embodiment of the confectionery piece is disclosed in the specification (See Examples 1-3, pages 17-21), which provides ample support for a claim to a confectionery piece consisting essentially of one oral comfort region and one salivation region. In fact, that is the present preferred commercial embodiment of the invention.

Applicants respectfully request reconsideration of the rejection of claims 1 - 21 over the combination of WO 99/59427 (WO '427) and U.S. Patent No. 6,231,900 (Hanke), in light of these remarks.

The key feature of the present claims that has not really been addressed in the rejections is the product configuration: that the salivation agent is concentrated in a discrete and separate region of the product such that salivation is enhanced; and an oral comfort ingredient is provided in another region. While an acidulant evenly distributed throughout a product may cause a certain amount of salivation, the effect is enhanced if the same amount of acidulant is provided in discrete pockets, for reasons unrelated to the overall concentration of salivation agent in the product. This is because a high concentration of acidulant in isolated pockets increases the "punch" of the acidulant in that localized area, causing oral manipulation of the candy in the mouth. For example, a given amount of acid which might make a confection "tart" if it is distributed throughout the product, if it is concentrated in discrete regions causes a much more tart, even irritating, sensation in those regions. This causes mechanical motion of the piece in the mouth, increasing salivation. Of course, without an oral comfort region, the high localized concentration of acid in the salivation regions would not be well tolerated. Thus, the

invention does not reside so much in the discovery of an individual salivation agent, or a level of an agent that yields a certain salivation effect, but in a product configuration that enhances a salivation effect. This aspect of the invention has been emphasized by the foregoing amendment in view of the Examiner's remarks.

A presently contemplated commercial embodiment of the invention consists essentially of one oral comfort region and one salivation region. This embodiment is claimed in new claim 22.

That acids have been used to promote salivation is clearly known in the confectionery art (see e.g. WO '427, line 19). Likewise, the segregation of ingredients in a confectionery product is not by itself novel; encapsulation has been practiced for many years, and in many cases incompatible ingredients in a product are segregated simply by virtue of the fact that they are different ingredients. However these observations do not provide sufficient "motivation" to make the combination asserted by the Examiner.

Specifically, WO '427 teaches a method for segregating acid components in a comestible product from the flavorings in the product which may be acid sensitive (see page 2, lines 19-21). The acid components are co-processed with a sugar alcohol to prevent degradation of the acid-sensitive ingredients prior to consumption (page 2, lines 21-25). However, when the ingredients are in the mouth, the flavor and acid are perceived at the same place and at the same time. (See page 4, lines 24-27.) Thus, the ingredients are not in separate regions. WO '427 teaches away from providing them in separate regions, because they must be tasted together. As demonstrated in the December 16, 2002

interview, WO '427 teaches an effectively uniform concentration of the relevant ingredients throughout the product.

Hanke, whether taken alone or in combination with WO '427 does not render obvious the claimed invention. Hanke does not disclose separate regions with a salivation agent and oral comfort ingredient, respectively. Instead, Hanke discloses a confectionery product having a region with a cooling composition and a region with a flavor composition. Cooling compositions are known in the art (see Hanke, col. 4, line 1, col. 5, line 63), and are clearly understood in the art to be distinct from an oral comfort ingredient (see the present specification at least at page 12, lines 1-2). Thus, Hanke does not suggest the macroscopic segregation of the components recited in the present claims.

A *prima facie* case of obviousness under 35 U.S.C. § 103, requires a factual inquiry into the differences between the claimed invention and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). To the extent that none of the references discloses the interaction of an ingredient that will effectively lubricate or coat an oral cavity and one that will increase salivation, the Office Action does not address relevant differences between the claimed invention and the prior art. No combination of the cited references yields a confection having a salivation agent and an oral comfort ingredient provided in separate regions, such that the concentration of salivation agent in a particular region causes increased oral manipulation which enhances salivation, while the oral comfort ingredient, located in a separate region, lubricates or coats the oral cavity.

Further, a *prima facie* case cannot ordinarily be made out where the references themselves teach against the asserted combination. *See, e.g. W.L. Gore v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). In the present case, WO '427 teaches the presence of an acidulating agent to enhance a flavor component. Accordingly, these components are provided mixed together in the product (albeit segregated on a microscopic scale). This is opposite in effect from the claimed confection, which requires separation of components. Hanke does not teach a salivation region at all. Neither reference, alone or in combination, teaches or suggests the claimed confection.

For at least the foregoing reasons, applicants submit that the present claims are patentable over the cited references and respectfully request allowance and prompt passage of the application to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our address given below.

Respectfully submitted,



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APPENDIX

1. (Amended) A confectionery product comprising:

(i) [a] one or more salivation [region] regions comprising a salivation agent in an amount effective to aid in the stimulation of the flow of saliva in an oral cavity and a salivation region confectionery base; and

(ii) [an] one or more salivation oral comfort [region] regions [that is separate and distinct from said salivation region, said oral comfort region] comprising an oral comfort ingredient in an amount effective to lubricate, coat or moisten said oral cavity and an oral comfort region confectionery base,

wherein the salivation agent is concentrated in the one or more salivation regions maintained as discrete and separate regions to enhance salivation,
and the oral comfort ingredient is concentrated in the one or more oral comfort regions.

22. (New) The confectionery product of claim 1, consisting essentially of one salivation region and one oral comfort region.

23. (New) A confectionery product comprising:

(i) one or more salivation regions comprising a salivation agent selected from the group consisting of acidulents, cooling compounds, salts, salt enhancers,

monosodium glutamate, monosodium glutamate enhancers, flavors and mixtures thereof in an amount effective to aid in the stimulation of the flow of saliva in an oral cavity and a salivation region confectionery base; and

(ii) one or more oral comfort regions comprising an oral comfort ingredient selected from the group consisting of lipids, proteins, surfactants and mixtures thereof in an amount effective to lubricate, coat or moisten said oral cavity and an oral comfort region confectionery base,

wherein the salivation agent is not uniformly distributed throughout the product but is concentrated in the one or more salivation regions maintained as discrete and separate regions to enhance salivation,

and the oral comfort ingredient is concentrated in the one or more oral comfort regions.

24. (New) A confectionery product comprising:

(i) one or more salivation regions comprising a salivation agent in an amount effective to aid in the stimulation of the flow of saliva in an oral cavity and a salivation region confectionery base; and

(ii) one or more oral comfort regions comprising an oral comfort ingredient in an amount effective to lubricate, coat or moisten said oral cavity and an oral comfort region confectionery base,

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wherein the salivation agent is not uniformly distributed throughout the product but is concentrated in the one or more salivation regions to cause movement of the product in the oral cavity,

and the oral comfort ingredient is concentrated in the one or more oral comfort regions.

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